UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/175,748	10/20/98	HASTINGS	C

EXAMINER	
FAULKNER, D	
ART UNIT	PAPER NUMBER
1617	2

HM12/0128

JOHN B LUNGMUS
TILTON FALLON LUNGMUS & CHESTNUT
SUITE 960
100 SOUTH WACKER DRIVE
CHICAGO IL 60606-4002

DATE MAILED: 01/28/00

BEST AVAILABLE COPY

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1996-410-238/40050

Detailed Action
112 Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1.) Claims 1 – 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling fora protein that is water extracted, does not reasonably provide enablement for a protein on a moisture free basis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The applicant has not described the term "moisture free basis" in a way that depicts the breadth of the claims. Subsequently, one of ordinary skill in the art would not be apprised of the nature of the invention, nor of the state of the prior art. The specification has not provided any direction as to how to calculate a protein on a moisture free basis. Therefore it would require undue experimentation to make the invention based on the content of the disclosure. The applicant can overcome this rejection by limiting the language to the terms that applicant is enabled for. Applicant is enabled for those methods of mixing the protein based dietary supplement particularly disclosed in the specification. See ex. P. 5 lines 3-5, and examples 1-3 therein. The

determination of additional methods for which the claimed protein would be made and utilized would require undue experimentation by one of ordinary skill in the art.

2.) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant refers to a protein isolate provided on a moisture free basis. It is unclear what applicant means by the words "moisture free basis". Applicant can overcome this rejection by deleting this terminology from the claims.

Claims 1-10 are also indefinite due to the inclusion of the relative term, "essentially," in line 2 of claims 1 and 10.

Detailed Action

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a limitation using the words that said "amino acid premix includes all seven of said amino acids of said group." This language is confusing in that it does not refer to which particular amino acids that applicant is intending to encompass. For example carnitine is synthesized in the liver from the essential amino acids-lysine and

methionine, (however the claim has more than 7 amino acids.) The applicant can overcome this rejection by removing the words "all seven of said amino acids of said group and inserting the particular amino acids that applicant intends to encompass.

103 Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 - 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smidl et al., U.S. Patent 5,438,042 in view of Majeed et al., U.S. Patent 5,536,506, further in view of Pera, 5,944,012 and Beale, U.S. Patent 5,756,469.Smidl teaches enteral nutritional compositions comprising 4-30% lipid component, 65-80% carbonhydrate component and 16-25% of a protein component. See abstract. The lipid component may be based on the long chain fatty acids and medium chain triglycerides (MCT'S) with fatty acids chains of 6-12 carbon atoms. See col. 4 lines 23-27. The lipid component also comprises omega-6 poly-unsaturated fatty acids (i.e. linoleic acid) See col. 4 lines 29-30. The carbohydrate sources include vegetables, starches, glucose, and maltodextrins. (See col. 4, lines 45-56. Additional flavorants are shown in col. 7 lines 65- col. 8 line 7. The protein source comprises a source from several conventional sources, see col. 4 lines 56-64. The protein source is based on free base amino acids, ingestible salt form, partially hydrolyzed protein form or intact protein form. The constituents are amino acids. See col. 5 line 5. The particular amino acids that are included of the composition are: carnitine, (see col. 7 lines 15-36.), L-glutamine, L-leucine, L-arginine acetate, L-Lysine acetate, L-alanine, and glycine. See col. 8, col. 9, and col. 10 tables. Ornithine is described in col. 2 line 38.

The Smidl enteral composition additionally includes vitamins and minerals. See col. 9 lines 63 - col. 10. See also claim 1. Smidl differs from the applicants claims in that he fails to describe additional nutrients and vitamins, such as creatine monohydrate, grape seed extract, coenzyme Q10, ubiquinone J. piper nigum extract, and alpha lipoic acid.

Majeed et al. teaches nutrients and nutritional supplements which comprise piper nigum extract, see claims 2 and 11. Majeed does not teach the grape seed extract, per see, although he teaches the nutrient sources found in grape seed extract -- see quercitin and rutin which are flavanoids, see col. 7 lines 49-50 in table examples. Majeed includes coenzyme Q10 in the nutritional formulation, as well as including several amino acids, see col. 5 lines 17-22. Antioxidants and L-carnitive is shown in col. 7 line 56, and claim 5. Pera teaches a combination of antioxidants in a dry powder nutrient formulation. These antioxidants include alpha lipoic acid and coenzyme Q10. See abstract and col. 8 lines 60 through col. 9 line 1.

Beale teaches compositions that are used to increase protein in a mammal which include isoflavones creatine monohydrate, and phosphatidyl serine, combined with amino acids and antioxidants. See claims.

One of ordinary skill in the art would have been motivated to combine the teachings of Smidl, Majeed, Pera, and Beale in one nutritional nutrient formulation. The reason for combining the teachings is given by the fact that all formulations are nutritional compositions for consumption by mammals in order to increase or supplement nutrients, proteins, carbohydrates, and lipids. The average skilled artisan would have been motivated to look in the nutritional formulation art area to find suitable excipients for nutrient formulations.

Although each and every exact percentage has not been demonstrated for each and every excipient, the selection of active ingredients and nutrients are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the concentration and form of each ingredient to optimize the effect desired, and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability

Any inquiry concerning this communication should be directed to Diedra Faulkner at telephone number (703) 305-4043.

D. Faulkner:jmr

Jan. 03, 2000

Jan. 05, 2000

D. Faulkner

MINNA MOEZIE
PRIMARY EXAMINER